

THE SUBJECT MATTER CLAIMED IS:

Sub
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1. An aerosolizable, spray-dried powder formulation for pulmonary delivery comprising a therapeutically effective amount of FSH.

2. The formulation of claim 1, containing less than 5% FSH degradation products.

3. The formulation of claim 1, further comprising a pharmaceutically acceptable excipient.

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4. The formulation of claim 3, wherein said excipient is selected from the group consisting of carbohydrates, amino acids, polypeptides, buffers, and salts.

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5. The formulation of claim 4, wherein said excipient is a carbohydrate selected from the group consisting of galactose, mannose, sorbose, lactose, trehalose, cyclodextrin, raffinose, maltodextrins, dextrans, mannitol, and xylitol.

6. The formulation of claim 4, wherein said excipient is an amino acid.

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7. The formulation of claim 6, wherein said amino acid is selected from the group consisting of alanine, glycine, tryptophan, tyrosine, leucine, and phenylalanine.

8. The formulation of claim 6, wherein said amino acid is a hydrophobic amino acid.

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9. The formulation of claim 8, wherein said amino acid is effective to increase the dispersibility of the formulation.

10. The formulation of claim 4, wherein said excipient comprises HSA.

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11. The formulation of claim 4, wherein said excipient comprises a buffer.

12. The formulation of claim 4, comprising from about 0.05 to about 99 percent by weight FSH.

13. The formulation of claim 1, wherein said powder comprises particles with an average particle of less than 10 microns MMD.

14. The formulation of claim 13, comprising particles sized from about 1.0 - 5.0 microns MMD.

15. The formulation of claim 1, wherein said powder comprises particles sized from about 1.0 - 5.0 microns MMAD.

16. The formulation of claim 1, further characterized by a delivered dose of greater than about 30%.

17. The formulation of claim 1, aerosolizable in a dry powder inhaler.

18. A method of treating a disease state responsive to treatment by FSH, said method comprising administering by inhalation to a subject in need thereof the formulation of claim 1 in aerosolized form.

19. The method of claim 18, wherein said administering step comprises dispersing said powder formulation in a gas stream to form an aerosol and inhaling.

20. A method for preparing a FSH dry powder composition suitable for pulmonary delivery, said method comprising spray drying an aqueous mixture comprising FSH under conditions effective to provide a respirable, spray dried FSH powder.

21. The method of claim 20, wherein the powder formed in said spray drying step contains less than 5% FSH degradation products.

22. The method of claim 20, wherein said aqueous mixture further comprises a
5 pharmaceutically acceptable excipient.

23. The method of claim 20, wherein 98% or more of the mass of the spray dried powder comprises particles having a diameter of 10 microns or less.

10 24. The method of claim 20, wherein 90% or more of the mass of the spray dried powder comprises particles having a diameter of 5 microns or less.

15 25. A respirable powder produced by the method of claim 20.